Summary of the Hospital Beds and Vulnerable Patient Meeting Minutes
November 1-2, 2001
Baltimore, MD

Day 1 - November 1, 2001

The meeting opened with a welcome from Dr. Lireka Joseph of the FDA's Center for Devices and Radiological Health and our host, Jeane Nitsch of The Center for Medicare and Medicaid Services. Dr. Joseph emphasized to the group the importance of an effective execution of the very impressive issue resolutions that have been developed by the group.

Discussion of Interaction between FDA and CMS – Jeane Nitsch

Ms. Nitsch mentioned that the MOA is currently with the higher ups at CMS. Jeane thought that she might have a response from her Agency by the end of the Conference. She also mentioned that even if CMS is unable to sign the MOA, CMS support of this project is not diminished.

Clinical Guidelines - Janet Myder

Ms. Myder reported that we still need the Legal Team consensus before moving this document to the next phase of review. RE: CMS, JCAHO, VA, and CARF.

There may also be a need to review the Clinical Guidelines for intellectual property (IP) or copyright issues. This would need to be accomplished by the Legal Team as well. There was a discussion among the group regarding whether Ms. Braun's written report indicated that the Legal Team wanted to get the IP or copyright matters settled before they completed their overall (consensus) feedback on the Clinical Guidelines. The group agreed that there is a need to work out a timeframe with Ms. Braun and Ms. Kyle to determine how the intellectual property review might affect the deliverable endpoints.

Ms. Myder noted that the Clinical Guidelines were intended to be recommendations to caregivers and not issued as a mandate. She also reported that the decision tree of the guideline is still in draft. This would be a pocket version of the overall Clinical Guidelines.

Dr. Joseph will contact Ms. Braun to see how the HBSW can assist the Legal Team with their review to help meet the expected deliverable dates.

Finally, Ms. Myder reported that the remaining action items for the completion of the Clinical Guidelines are:

1. Intellectual Property (IP)/copyright review
2. Legal Team Consensus
3. CMS, JCAHO, VA and CARF policy review
4. Guidelines publication and dissemination

HBSW Dimensional and Assessment Guidelines – Lance Lockwood

Mr. Lockwood reported on the status of the HBSW Dimensional Guidelines since the March meeting of HBSW. The first draft of the document, dated 19JUL01, was sent to FDA document management on 20JUL01. FDA personnel replaced the first draft photos with photos excerpted from the training video. The final draft HBSW document was completed and transmitted via email 28SEP01 (although the document cover sheet date remained 19JUL01).

One open issue regarding the copyright implications is the use of Dr. S. Miles' entrapment graphics. Julie Braun's report indicated that the publisher of these graphics has been contacted for permission to use these pictures. HBSW awaits the journal publisher's response. It should be noted that alternative means of producing similar graphics are available to HBSW if needed.

Dr. Rick Rader has offered to have Exceptional Parent (EP) publish a monograph on the Dimensional and Assessment Guidelines. Examples of other EP monographs were shared and passed on to Beryl Goldman for review.

Dr. Joseph discussed the two levels of FDA Guidance's. Level 1 documents require a public comment period prior to issuance as a final document. Level 2 documents have a public comment period concurrent with issuance of the document. Comments can be submitted at any time but are addressed at a point in the future. After discussion the group agreed it that this document needs to be processed as a Level 1 document. Dr. Joseph indicated that she was confident that the Agency would choose to process our document as a Level 1.

VISN 8 Bed Dimension Study – Gail Powell-Cope

Dr. Powell-Cope explained the results of a comprehensive legacy equipment study performed by VA VISN 8. The over-arching observation from the study was that the majority of bed systems do not meet the proposed dimensional criteria. Additionally, a one-year review of patient injuries that included both patient entrapments and patient falls, demonstrated that patient falls are far more prevalent than entrapment; e.g. out of (692) recorded events (4) were entrapments and the balance were falls at the recording facilities.

Dr. Powell-Cope's analysis suggested that the falls portion of these events cost $1.8 million in additional medical care. She suggested that the cost of the falls portion of these reported events should help policy makers to develop cost-benefit models for any proposed investment in bed safety interventions.

Corrective Action Guide (CAG) – Gail Powell-Cope

Dr. Powell-Cope presented the following unresolved issues (See memorandum 10/31/01) within the document. These issues were extensively reviewed by HBSW and changes to the CAG were made during the meeting. Dr. Powell-Cope will send out a revised version for the group to review.

Michigan regulatory Update – Tom Martin

Mr. Martin reported that no new statutory guidelines have been produced by Michigan. Copies of Michigan's Interim Guidelines were made available to HBSW. Michigan state regulators are not enforcing the Interim Guidelines, however, the Interim Guidelines are still in their original form awaiting HBSW Guidelines acceptance. Mr. Martin reported that Michigan is waiting until the FDA Dimensional and Assessment Guidance is available before implementing the new State regulations.

The original interim guidelines are what MI state surveyors are using today, however, where the interim guidelines do not match HBSW Dimensional and Assessment Guidelines, surveyors are looking at the care-plan outlined by the facility caregivers. As long as the care plan documented that a patient/resident clinical assessment had been performed, the non-compliant equipment aspects were not being enforced (i.e., no fines are being levied)

A question was raised about whether any financial impact study had been performed by the State of Michigan. Mr. Martin reported that this mandate was not funded by the Michigan legislature and cost estimates had not been performed.

Rolling Out the HBSW Bed Safety Dimensional Assessment Programs: Setting the Stage. - Susan Meadows, FDA

Ms. Meadows presented a discussion outline to introduce issues and approaches to be considered when implementing the HBSW Bed Safety Dimensional Assessment Program for legacy equipment at the facility level. All of the HBSW products would be included and used in the implementation.

Ms. Meadows suggested several outreach targets and the various regulatory/standards organizations that have a stake in this effort. Additionally, Ms. Meadows suggested several potential implementation partners for this outreach effort. And finally, she listed the Next Steps towards the completion of this project.

Following Ms. Meadow's presentation, HBSW engaged in a discussion that included the following questions and answers:

Question: Can caregivers/facilities choose to use a means other than the cone/cylinder tool to make their in-house equipment assessments?
ANS: Yes. However, caregivers and facilities must be sure that the other means used is consistent with the standard measurements, materials and configuration of the HBSW cone/cylinder.

Question: Will CMS surveyors be using the tool?
ANS: No. CMS surveyors enforce CMS regulations and interpretive guidelines and they will not assess the bed for dimensional compliance with HBSW guidelines.

Question: Why should a facility purchase a tool?
ANS: 1. A basis for responding to surveyor's claim that a bed system is out of compliance.
2. Ability to assess equipment usage changes that occur over time.

Note: The Nat'l Assoc. of Health Facility and Survey Agencies would be a good place to influence individual state's acceptance of HBSW D&AG.
Both Carol Benner, Pres. 410-764-2750 or 402-8001 and Past Pres, Mike Tripple, email: mike.tripple@health.states.mn.us would be good contacts to this organization.

HBSW Bed Safety Assessment Instruction Video – Susan Meadows, FDA

Ms. Meadows presented the status of the videotape outlining its five objectives:

- Introduce bed safety entrapment issues
- Identify entrapment zones
- Specify recommended dimensions
- Identify bed safety assessment equipment
- Present the HBSW bed safety assessment procedures

Ms. Meadows indicated that this video was based on the draft Preamble and the Issue Gruop 3 instructions for bed safety assessment.

She then presented the draft's 1st cut footage. Ms. Meadows indicated that this video was not yet a finished product and still required additional editing.

Dimensional and Assessment Guidance– Pat Cricenti, FDA

Ms. Cricenti reported that the Dimensional And Assessment Guidance is currently making its way through the FDA approval process. Jay Rachlin indicated that we have until next Friday, 09NOV01, to make any last minute changes to this document.

It is not certain when the Dimensional And Assessment Guidance will reach the Federal Register. Ms. Cricenti assured HBSW they would be the first to know when this document will be available for public comment. Additionally, Ms. Cricenti's presentation included the FDA website information where guidance documents may be viewed.

IEC/ISO JWG3 - Hans Werner Zeller, VDE

Mr. Zeller provided an overview of the International Standards development process. He specifically outlined JWG3's planned completion schedule for the revised Medical Beds standard outlined below.

2002 – Committee Draft (CD) #1
2003/04 – Committee Draft for Vote (CDV)
2005 - FDIS Final Draft International Standard
2006 – Publish Final International Standard

Members of HBSW are also members of IEC and will work to harmonize the two standards. Mr. Zeller was interested in working towards one strong standard. The IEC will comment to FDA on the proposed dimensional guidance during the public comment period.

Day 2 - 02NOV01

Assessment Kits – Mark Bruley, E.C.R.I.

Mr. Bruley provided an extensive update on the various Kits planned for production by HBSW through ECRI. Rough cost estimates of the various Kit components (A. below) and the planned completion dates (B. below) were worked through by the entire group.

A. Cost estimates for the Kit (Nov 2001, subject to change)
ECRI minimum estimated production costs: $165 - $185
Estimated selling price: $200 - $300

Component Cost Estimates

• Three ring binder	$ 2
• Tab dividers	$ 1
• Binder cover and spine inserts (printing/inserting)	$ 1
• Document printing (~100 pages)	$ 10

Documents for inclusion —
- Preamble
- Forward explaining HBSW interim documents
- Dimensional guidelines
- Data collection sheet
- Clinical guidelines
- Corrective action guidance
- HBSW brochure
- Instruction sheet for Tool
- OTHER

• Scale with attached handle and hook	$ 20
• Video for clinicians (with label, cover, shrink-wrapped)	$ 8
• Tool: Cone/Cylinder (with strap)	$ 60-80
• Shipping	$ 15
• Order fulfillment / tracking / inquiries	$ 45
• Shipping box and packing	$ 3
Rough Estimates of Production Costs	$165—$185

Production overhead costs not yet estimated:

- Storage for stock (publications, scales, tools, binders, ship cartons/packing, printed matter, etc.
- Kit assembly labor
- Inventory control
- Insurance
- Incoming shipping charges for tools, scales, binders, etc.

Brochure Printing: $4,000 per 25,000 copies

B. Estimated Kit Availability Date (using HBSW prelim documents)

- Cone/Cylinder w/ coating: Jan02 (need safety instruction sheet)
- Clinician Video: JAN02
- Scale: JAN02
- Documents included in kit: (~ 100 pages)
  1. Dimensional Guidelines: NOV01
  2. Data collection sheet: DEC01 (mechanical and electric beds)
  3. Clinical Guidelines: APR02
  4. Corrective Action Guidance: JAN02
  5. Preamble:
  6. Foreword explaining HBSW interim documents: MAR02 (Liz, , Al, Jackie, VA, Jay and Joan)
  7. Brochure: NOV01 (12,000 inventory)
- Second wave of products
  1. Family video: 2nd wave The VA agreed to take the lead on this video.
  2. Consumer brochure: 2nd wave
  3. Consumer video: 2nd wave
  4. Laminated pocket reference card for Clinical Guidance (licensed professionals): 2nd wave
  5. Laminated pocket reference card for Clinical Guidance (unlicensed professionals): 2nd wave
- Assemble the three ring binder: DEC01

Complete Kit Availability: June 2002 (best case)

Dr. Powell-Cope requested the minutes reflect that she was opposed to having the assessment tool weigh as much as it does due to the potential for musculoskeletal injuries with its use, and that if it cannot be re-designed, text needs to be developed explaining safe handling procedures, proper body mechanics and assessment scheduling to avoid injuries.

Kit that includes 2nd wave items would be available after 1-2 years experience with the initial Kits usage.

C Logo

Jay Rachlin agreed to send the logo to Mark in electronic form.

D. IP/Copyright Issues

Julie Braun and the Legal Team are coordinating these issues.

Discussion of Intellectual Property issues - Julie Braun, J.D.

Ms. Braun provided a written report of the status of the items under review by the Legal Team. It was clearly the consensus of the HBSW that the Legal Team's input to all of HBSW documents is important to the success of the Workgroup's products being widely received and accepted.

Preamble Document - Dr. Liz Capezuti, Emory University

Dr. Capezuti joined the group by phone and reported that the Preamble for the HBSW products was near completion and would be ready for HBSW review within the next two weeks.

Distribution of the Clinical Guidelines - Beryl Goldman, Kendal Corporation

Ms. Goldman discussed distribution of the Brochure, "A Guide to Bed Safety". She then led the group through several items to be resolved. The discussion of the HBSW outreach efforts to include publication's distribution plans for HBSW products and funding for future efforts.

It was decided that a small Implementation Steering Committee should be formed to work on and move forward the outreach portion of the HBSW project. The Steering Committee would follow S. Meadows' video rollout format. RE: Regulatory/Oversight/Standards, Outreach Campaigns, Training Programs and Adoption/Dispersion.

The following HBSW participants agreed to join the Steering Committee: Beryl Goldman (chair), Susan Meadows, Mary Lou Pijar, Laurie Rappl, Audrey Nelson (or designee) and Lance Lockwood. It was suggested that the Steering Committee meet, by phone, January 2002.

Wrap-up and Homework Assignments - Dr. Lireka. Joseph, FDA

Dr. Joseph reviewed the action items that had been captured throughout the course of the meeting. She mentioned that we have received lots of good comments during this meeting but that we now have to freeze the documents so that we can now move forward with them. The following action items were identified:

- Clinical Guidelines

1. Complete the intellectual property/copyright review
2. Reach consensus by the Legal Team
3. Policy review by CMS, JCAHO, VA, and CARF
4. Publish and disseminate the Guidelines

- Dimensional and Assessment Guidelines

1. A final call for comments was extended to all members of HBSW with a due date of November 9th, 2001
2. Reword the test method for Zone 7
3. Add a cautionary statement about accessory bed equipment when measuring for entrapment, e.g. IV poles
4. Consider the need to edit the video footage if Zone 7 measurement technique is changed
5. Draft a Foreword to the HBSW guidelines to include a definition of a hospital bed and to discuss the exclusion of specialty beds from this guidance. The initial members volunteering to serve on this subcommittee are Al deRichmond, Jackie Robertson, Gail Powell-Cope, Jay Rachlin and Joan Todd.
6. Lance to follow-up with Julie Braun on the trademark and use of drawings issue

- Corrective Action Guide

1. Send out a revised version to HBSW for review

- HBSW Implementation Steering Committee

1. Begin to formulate plans for implementation of HBSW work products for the March 2002 meeting. The initial members volunteering to serve on this subcommittee are Beryl Goldman, Audrey Nelson, Mark Bruley, Liz Capezuti and Mary Lou Pijar. Others are needed and encouraged to join.

- New Members

1. Jay Rachlin will send a copy of the Memorandum of Agreement to the new members joining HBSW for their concurrence with the MOA.

- A subcommittee was formed to begin developing a second video targeted for patients and family members. Members on this subcommittee include Beryl Goldman, Gail Powell-Cope, Sarah Burger, Lauren Jones, Bill Kubat, and Tom Whelan.

Finally, our next HBSW meeting has been scheduled for March 8-9, 2002. This is to follow the VISN 8 Patient Safety Center's conference on "New Developments in Hospital Bed Safety" in Clearwater, FL and will venue at the Hilton Clearwater Beach Resort.